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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/799,910 02/13/97 FALB

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EXAMINER

HM12/0425

PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036

NGUYEN, D

ART UNIT

PAPER NUMBER

1633

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/799,910

Applicant
Falb et al.

Examiner
Dave Nguyen

Group Art Unit
1633



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 103-107 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 104 is/are allowed.

☒ Claim(s) 103 and 105-107 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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The request filed on November 29, 1999 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/799,910 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 90-96 have been canceled by the amendment dated June 23, 1999.

Claims 71, 74, 77-89, and 97-102 have been canceled by the amendment dated November 29, 1999.

Claim 70 has been canceled; and claims 103-107 have been added by the amendment dated Feb. 17, 2000.

Claims 103-107, to which the following grounds of rejection are applicable, are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 103, and 105-107 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention encompassing any and/or all polynucleotide sequences including coding regions, introns, 5' and 5' regulatory elements, other untranslated regions, full length ORFs, structurally unrelated DNA sequences, and partial DNA sequences of genes other than nucleotides 211-468 of SEQ ID NO: 9.

The claims encompass a genus of "polynucleotide sequences" comprising nucleotides corresponding to coding regions, introns, 5' and 3' regulatory elements, and untranslated regions of the genes, full-length encoded cDNA and/or genes (claim 103), and structurally unrelated DNAs, and partial DNA sequences of genes other than nucleotides 211-468 of SEQ ID NO: 9 (claim 105).

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An adequate written description of the invention defined by the claims, e.g. genus of polynucleotide sequences and/or genes and/or unrelated DNA sequences that hybridize to nucleotides 211-468 of SEQ ID NO: 9, requires more than a mere statement that it is part of the invention and reference to a knowledge in the art as to a partial open reading frame (ORF) as set forth in SEQ ID NO: 9; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of the claimed genus. The specification describes an isolated cDNA fragment (nucleotides 211-468 of SEQ ID NO: 9) obtained from a human endothelial cell library which was induced under shear stress conditions. Nucleotides 211-468 of SEQ ID NO: 9 is asserted to be homologous to the mouse gly96 cDNA, which encodes a cytokine inducible glycosylated protein expressed in mouse lung, tested, and uterus. Further, the specification indicates that it would be reasonable to infer that the partial sequence of nucleotides 211-468 of SEQ ID NO: 9 can be used as a probe to isolate the mouse gly96 cDNA. A search of prior art indicates that nucleotides 211-468 of SEQ ID NO: 9 as of Feb. 16, 1996 is novel and unobvious and no associated genomic clones have been identified, and that other than the mouse gly96 cDNA, no other unrelated cDNA sequences has greater than 50% similarity to the disclosed nucleotides. A review of the specification indicates that elements which are not particularly described, including coding regions, introns, 3' and 5' regulatory elements, other untranslated regions, full length ORFs, structurally unrelated DNAs, and partial DNA sequences of genes other than nucleotides 211-468 of SEQ ID NO: 9. There is no actual reduction to practice the full scope of the claimed invention, clear depiction of the claimed invention in the drawings or complete detailed description of the structure. Considering all disclosed distinguishing identifying characteristics, there is a disclosure of only nucleotides 211-468 of SEQ ID NO: 9 as well as the function of the nucleotides as a probe for the mouse gly96 cDNA.

However, there is no known or disclosed correlation between this function and the structure of the non-described coding regions, introns, 3' and 5' regulatory elements, other untranslated regions, full length ORFs, structurally unrelated DNAs, and partial DNA sequences of genes other than nucleotides 211-468 of SEQ ID NO: 9. Furthermore, there is no additional disclosure of physical and/or chemical properties.

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Weighing all factors in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that application was in possession of the genus which comprises nucleotides 211-468 of SEQ ID NO: 9. Note that claiming a full-length coding sequence, gene, regulatory sequences, and unrelated cDNA sequences that achieve a result without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). In view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed genus other than a DNA sequence consisting of nucleotides 211-468 of SEQ ID No: 9.

Claims 103, and 105-107 are also rejected under 35 U.S.C. 112, first paragraph because the specification is only enabling for claimed invention as recited in claim 104. The specification is not enabling for the claimed subject matter being sought in claim 103, and claims dependent therefrom.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possessing of the genus of polynucleotide sequences as recited in the claims) for the reasons set forth above, one skilled in the art would not know how to use and make the claimed invention so that it would operate as intended without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 106 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 106 is indefinite in the recitation of "peptide comprising the polynucleotide" because it is not apparent as to how a polynucleotide is contained in a peptide, since a peptide is a amino acid sequence while a polynucleotide is a nucleic acid sequence.

Claim 104 is allowable because the prior art of record does not teach or suggest the polynucleotide as recited in the claim.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Dave Nguyen* whose telephone number is (703) 305-2024.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.



Dave Nguyen

Patent Examiner

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